4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-1466]

Good Manufacturing Practices for Cosmetic Products Listening Session; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a virtual listening session entitled "Good Manufacturing Practices for Cosmetic Products Listening Session." The purpose of the listening session is to consult cosmetics manufacturers, including smaller businesses, consumer organizations, and other experts, to inform Agency efforts to develop regulations to establish good manufacturing practices for facilities that manufacture or process cosmetic products distributed in the United States.

DATES: The virtual listening session will be held on June 1, 2023, from 10 a.m. to 1 p.m. Eastern Daylight Time (EDT) or until after the last public commenter has spoken, whichever occurs first. Submit requests to make oral presentations at the listening session by 6 p.m. EDT, May 18, 2023. Either electronic or written comments on this listening session must be submitted to the docket by July 3, 2023. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Additional details, such as registration information, are available at https://www.fda.gov/cosmetics/cosmetics-news-events/public-meeting-good-manufacturing-practices-cosmetic-products-06012023.

FDA is establishing a public docket for this listening session. You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m.

EDT at the end of July 3, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2023-N-1466 for "Good Manufacturing Practices for Cosmetic Products Listening Session." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Deborah Smegal, Office of Cosmetics and Colors, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., Rm. 1037 (HFS-125), College Park, MD 20740, 240-402-1130, (this is not a toll-free number), email: MoCRAGMPMeeting@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On December 29, 2022, the President signed the Consolidated Appropriations Act, 2023 (Pub. L. 117-328) into law, which included the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). Among other provisions, MoCRA added section 606 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), requiring FDA to establish by regulation good manufacturing practices (GMPs) for facilities that manufacture or process cosmetic products distributed in the United States. MoCRA specifies that these GMPs are to be consistent, to the extent practicable, and appropriate, with national and international standards, in accordance with section 601 of the FD&C Act (21 U.S.C. 361). Any such regulations shall be intended to protect the public health and ensure that cosmetic products are not adulterated. As required by MoCRA, before issuing rulemaking, FDA must consult with cosmetics manufacturers, including smaller businesses, consumer organizations, and other experts selected by FDA. Further, FDA must take into account the size and scope of the businesses engaged in the manufacture of cosmetics, and the risks to public health posed by such cosmetics and provide sufficient flexibility to be practicable for all sizes and types of facilities to which such regulations will apply. Such regulations must include simplified good manufacturing practice requirements for smaller businesses, as appropriate, to ensure that such regulations do not impose undue economic hardship for smaller businesses and may include longer compliance times for smaller businesses.

In addition, MoCRA added section 612 of the FD&C Act, which exempts certain small businesses from the GMP requirements.

FDA issued a draft guidance, entitled "Draft Guidance for Industry: Cosmetic Good Manufacturing Practices," (available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-cosmetic-good-manufacturing-practices) in 2013. We intend to withdraw or revise and reissue this draft guidance, as appropriate, based on the GMP rulemaking.

II. Topics for Comment

To facilitate input on good manufacturing practices for cosmetic products, FDA has developed a series of topics covering the types of information that we are interested in obtaining. In all cases, FDA encourages stakeholders to provide the specific rationale and basis for their comments, including any available supporting data and information.

Respondents need not reply to all topics listed. Please identify your answers as responses to a specific topic.

Topics Related to Good Manufacturing Practices

1. Identify any national or international standard (e.g., International Organization for Standardization (ISO) standard 22716:2007) and the extent to which it would be practicable for good manufacturing practice regulations for cosmetic products to be consistent with such standard. Please include whether there are specific items in the standard which are perceived to be burdensome or for which a less burdensome alternative exists that would protect the public health and ensure that cosmetic products are not adulterated.

2. Describe what constitutes sufficient flexibility within good manufacturing practices for cosmetic products to ensure regulations are practicable for all sizes and types of facilities to which such practices may apply. Please take into account the size and scope of the businesses engaged in the manufacture of cosmetic products and the risks to public health posed by cosmetic products.

3. Describe what constitutes simplified good manufacturing practices requirements for cosmetic products for smaller businesses to ensure regulations do not impose undue economic hardship.

4. Describe appropriate compliance times for good manufacturing practices regulations.

Topics Related to Economic Impact

5. To what extent are manufacturers of cosmetic products already following a national or international standard for good manufacturing practices? For manufacturers of cosmetic products that are not currently following such a national or international standard, what would it cost to implement good manufacturing practices consistent with such a standard?

6. Please provide reports or examples of adverse events or recalls associated with a cosmetic product that were linked to manufacturing practices. How would implementing good manufacturing practices impact the likelihood of recall of cosmetics products? How would implementing good manufacturing practices impact the likelihood of consumers experiencing adverse events from the use of cosmetics products? How would these impacts differ by type of cosmetic product?

III. Participating in the Listening Session

Registration: To register for the free virtual listening session, please visit the following website: https://www.fda.gov/cosmetics/cosmetics-news-events/public-meeting-good-manufacturing-practices-cosmetic-products-06012023. Registration may be performed at any time before or during the listening session.

Information on requests for special accommodations due to a disability will be provided during registration.

Requests to Provide Oral Presentations: During online registration you may indicate if you wish to present during the listening session. Requests to provide public comments during the listening session should be submitted by 6 p.m. EDT, May 18, 2023. We will do our best to accommodate requests to make public comments. Individuals and organizations with common

interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Based on the number of requests we receive, we will determine the amount of time allotted to each presenter (which we expect to be approximately 3 minutes) and the approximate time each oral presentation is to begin. We will select and notify participants at the time of registration, or by May 19, 2023. If selected for presentation, participants must email presentation materials to MoCRAGMPMeeting@fda.hhs.gov no later than May 22, 2023, 11:59 p.m. EDT. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Listening Session: This listening session will be webcast. Please register online (as described above). Registrants will receive a hyperlink that provides access to the webcast.

FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the listening session is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Dockets Management Staff (see **ADDRESSES**).

Dated: April 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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